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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,817	04/08/2005	Thomas A Alheidt	P-5856	9959

7590 11/22/2010  
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EXAMINER
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SHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

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11/22/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,817	<b>Applicant(s)</b> ALHEIDT ET AL.	
	<b>Examiner</b> LAURA C. SCHELL	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6, 18-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Laffy et al. (US Patent No. 5,373,971). Laffy discloses an I.V. flush syringe assembly (Figs. 10 and 11, this syringe is perfectly capable of being used to flush a syringe) comprising:

a barrel (Figs. 10 and 11, barrel 1) having an inside surface defining a chamber (Fig. 10 discloses fluid in chamber 2) for retaining fluid, an open proximal end (Fig. 11 discloses that the proximal end is open allowing the insertion of the plunger assembly) and a distal end (near where 1 is pointing to in both Figs. 10 and 11) including a distal wall with an elongate tip (46 in Fig. 11 for example) extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface having a contact area at the distal end of said barrel (the distal end of the barrel has an insider surface with a contact area, labeled in both Figs. 10 and 11 as 10), said contact area being a roughened portion of said inside surface (10 is the inside surface which are disclosed as being notches or teeth formed on the inside surface of the barrel (col. 8, line 66 through col. 9, line 3) which will dig into the plunger stopper 4 to retain

Art Unit: 3767

the plunger stopper in the position that the user advanced the plunger to and prevent the plunger from moving rearwardly. Since the inside surface has notches/teeth formed thereon, it can be said that the inside surface of the barrel is roughened),

a plunger including an elongate body portion having a proximal end (Fig. 11, proximal end is near 55), a distal end (near where 4 is attached to the plunger) and a flexible stopper (4) slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel (Fig. 11, the plunger is capable of meeting this functional language) said elongate body portion extending outwardly from said open proximal end of said barrel (Fig. 11);

wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber (Figs. 10 and 11 disclose that the notches/teeth create an area with a higher coefficient of friction as compared to the inside surface of the barrel towards the tip end of the barrel which does not include the teeth/notched area. As explained above, 10 is the inside surface which are disclosed as being notches or teeth formed on the inside surface of the barrel (col. 8, line 66 through col. 9, line 3) which will dig into the plunger stopper 4 to retain the plunger stopper in the position that the user advanced the plunger to and prevent the plunger from moving rearwardly.),

wherein the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position (Figs. 10 and 11 disclose that the outside diameter of 4 is equal to or less than the diameter of the interior surface of the barrel wall).

In reference to claim 5, Laffy discloses that the contact area further includes a plurality of annular deformations (Figs. 10 and 11 disclose that 10 (teeth/notches) are the annular deformations).

In reference to claim 6, Laffy discloses that the annular deformations are annular projections on said inside surface of said barrel (Figs. 10 and 11, projections 10).

In reference to claim 23, Laffy discloses that the stopper can be removed from said contact area after said stopper has contacted said distal wall of said barrel (if one were to use enough force, one could pull the stopper out of the barrel. The stopper may be damaged by doing this, but Applicant has not claimed such).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3767

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laffy et al. (US Patent No. 5,373,971) in view of Lynn (US Patent No. 5,522,804). Laffy discloses the device substantially as claimed including a tip cap (Fig. 11, cap 52) except for flush solution and needle assembly. Lynn, however, discloses a flushing syringe (Figs. 13 and 7c) with a tip cap (Fig. 7c, 124) and flushing solution in the chamber of the syringe, wherein the flushing solution is saline (Fig. 7c, 130; Fig. 7c discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), and better described by Col. 14, lines 20-30). Lynn further discloses a needle assembly attached to the end of the syringe (Fig. 7c, needle assembly 122). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Laffy with the use of saline solution and with the attachment of a needle assembly, as taught by Lynn, in order to provide the syringe with a flushing solution as well as a needle that can be attached to deliver the flushing solution, since the syringe of Laffy is structurally equivalent to a flushing syringe and is therefore perfectly capable of being used as a flushing syringe.

Art Unit: 3767

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laffy et al. (US Patent No. 5,373,971) in view of Greenwood (US Patent No. 5,120,314). Laffy discloses the device substantially as claimed including a stopper made from an elastic material (col. 1, lines 59-60), however, Laffy does not disclose the specific material used to make the stopper. Greenwood, however, discloses a similar device in which the stopper is made from rubber (col. 4, lines 57-58). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Laffy's stopper by forming it of rubber, as Laffy discloses that it is made from an elastic material, and it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

### ***Response to Arguments***

Applicant's arguments with respect to claims 4-6, 18-23 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/

Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767